

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vargas, Jaime; et. al.
Assignee: Cardica, Inc.
Title: Incision Tensioning System and Method for Using the Same
Serial No.: 09/764,218 Filing Date: January 16, 2001
Examiner: Victor X. Nguyen Group Art Unit: 3731
Docket No.: 032405-042

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APPEAL BRIEF UNDER 37 CFR § 1.192

Dear Sir:

Applicant submits this Appeal Brief pursuant to the Notice of Appeal filed in this case on December 4, 2003. This Appeal Brief is submitted in triplicate.

I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardica, Inc., as named in the caption above.

II. RELATED APPEALS AND INTERFERENCES

Based on information and belief, there are no appeals or interferences that could directly affect or be directly affected by or have a bearing on the decision by the Board of Patent Appeals in this appeal.

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III. STATUS OF CLAIMS

Claims 1, 10-16 and 18 stand finally rejected. These claims are set forth in the appendix attached hereto.

IV. STATUS OF AMENDMENTS

No amendments were filed after final rejection or are currently pending in this case.

V. SUMMARY OF THE INVENTION

Claim 1 is directed to a method for grafting a graft vessel to a target vessel. Such a method is useful in, for example, coronary bypass surgery, in which case the graft vessel is a vein such as the saphenous vein, and the target vessel may be a coronary artery. The claimed method includes forming an incision in the target vessel, placing incision tensioners within the incision in the target vessel, tensioning the incision in the target vessel with the incision tensioners, grafting the graft vessel to the target vessel while the incision is tensioned, and removing the incision tensioners from the incision after the grafting. The incision tensioners form and maintain a known geometry of the incision, to facilitate grafting. After the grafting has been completed to form the anastomosis, the incision tensioners are removed from the incision because they are no longer needed there. Claims 10-16 and 18 depend from independent claim 1, and thus add additional limitations to those present in independent claim 1.

VI. ISSUES

A. The Cited Art Does Not Read on the Claims

The Examiner finally rejected all pending Claims 1, 10-16 and 18. The sole reference cited for the rejection was Yencho *et. al.*, U.S. Patent No. 6,179,849 (“Yencho”), under 35 U.S.C. §102(e). (Office Action, Paper No. 15 (“Final Office Action”)). In that final rejection, the Examiner stated that Yencho shows “removing the incision tensioners (84, 86) is from the incision after the grafting.” (Final Office Action, page 2). However, while the Examiner identifies two structures in Yencho purportedly corresponding to the incision tensioners, Yencho does not disclose or suggest that those structures tension anything, much less an incision. Further, the Examiner does not accurately identify any disclosure in Yencho where removing those structures from the incision is taught or even suggested. Indeed, the Examiner cannot do so, because Yencho is directed to an anastomosis device that remains in place in the incision in the target vessel, and the identified structures 84, 86 in Yencho are a part of that anastomosis device. Thus, Yencho clearly fails to disclose at least one element of claim 1.

B. The Election Requirement Was Improper

Applicants do not appeal the restriction requirement, but do appeal the requirement to elect species, which Applicants traversed (Response to Office Action, November 8, 2002).

The Office Action of October 10, 2002 (Paper No. 9; “First Office Action”) set forth no reason for requiring election of species, instead merely stating that “election of species is required.” (First Office Action, page 3). However, MPEP 816 requires that “[t]he particular reasons relied on by the examiner for holding that the inventions as claimed are...distinct should be concisely stated. A mere statement of conclusion is inadequate.” (emphasis

added). Because no reasons were given and only a mere statement of conclusion was provided, the requirement to elect species failed to meet the standards of MPEP 816. Further, by requiring election of species without providing any reasoning for that requirement, the Examiner acted arbitrarily and capriciously in violation of the Administrative Procedure Act. Thus, the requirement to elect species should be withdrawn.

VII. GROUPING OF THE CLAIMS

All of Claims 1, 10-16 and 18 stand or fall together for purposes of this appeal. Claim 1 is independent, and claims 10-16 and 18 depend from that independent claim.

VIII. ARGUMENTS

A. The Cited Art Does Not Read on the Claims

Claim 1 claims a method for anastomosis comprising “forming an incision in [a] target vessel; placing incision tensioners within the incision in the target vessel; tensioning the incision in the target vessel with the incision tensioners; grafting the graft vessel to the target vessel while the incision is tensioned; and removing the incision tensioners from the incision after the grafting.” The incision tensioners are too large for permanent attachment to the target vessel, and would block or interfere with flow through the incision after grafting, so the incision tensioners are necessarily removed after the anastomosis is completed. (*e.g.*, Figures 3A-8, 14A-15B; page 11, lines 2-9; page 15, lines 5-12; page 19, lines 3-9).

In contrast, U.S. Pat. No. 6,179,849 to Yencho et. al. (“Yencho”) neither discloses nor suggests each and every element of claim 1. First, while the Examiner identifies two structures 84, 86 purportedly corresponding to the incision tensioners, Yencho neither discloses nor suggests that the U-shaped members 84, 86 apply tension to the target vessel or

any other tissue. Rather, the U-shaped members 84, 86 act in compression, not tension, to “clamp the side wall of the target vessel 102 between the U-shaped members and the side beams 88 of the frame 82.” (Yencho, column 5, lines 58-60). Yencho teaches nothing about tensioning tissue with those U-shaped members 84, 86, and thus the identification of those members 84, 86 as “incision tensioners” is erroneous. Thus, Yencho neither discloses nor suggests any structure that can be characterized as an incision tensioner.

Second, even if the structures 84, 86 are considered to be incision tensioners (which Applicants do not admit), Yencho neither discloses nor suggests removing incision tensioners from the incision after grafting. Instead, Yencho discloses an anastomosis device that connects a graft vessel to a target vessel and remains in tissue after grafting to accomplish that connection. (*e.g.*, Figures 4, 8, 10; column 4, lines 22-34; column 5, lines 28-32; column 5, lines 64-67). A “completed connection between the graft vessel 34 and the target vessel 42” is shown in Figure 4, where the anastomosis device remains in tissue to press “the edges of the graft vessel 34 against an exterior surface of the target vessel 42.” (column 4, lines 22-34). Thus, the entire anastomosis device of Yencho remains in place in the target vessel after anastomosis, unlike the claimed incision tensioners of claim 1.

Further, the Examiner does not accurately point out any disclosure in Yencho where removing incision tensioners from an incision after grafting is taught or even suggested. The Final Office Action states that “the Yencho reference teaches an anastomosis device that is capable of removing from the target vessel (labeled in col. 2, lines 5-24, col. 5, lines 52-67 and col. 6, lines 1-5).” (Final Office Action, page 4). However, those portions of Yencho cited in support of this statement fail to disclose or suggest removing an anastomosis device or any portion of an anastomosis device from an anastomosis site after the graft vessel has been connected to the target vessel. Instead, structures 84, 86 are “first and second pivoting

U-shaped members” that are part of an anastomosis device 80 that includes a frame 82. (Figures 9-10; column 5, lines 34-38). “Two lever arms 98 extend from each of the U-shaped members 84, 86.” (Figures 9-10; column 5, lines 44-45). To perform anastomosis, an end of the graft vessel is inserted into a portion of the anastomosis device 80, and the “U-shaped members 84, 86 are inserted through the opening 100 or incision in the target vessel 102.” (Figures 9-10, column 5, lines 52-53). Next, the lever arms 98 are rotated, pivoting the U-shaped members 84, 86 such that they “clamp the side wall of the target vessel 102 between the U-shaped member and the side beams of the frame 82.” (Figure 10; column 5, lines 54-60). Finally, the lever arms 98 lock in place. (Figure 10; column 5, lines 60-62). By locking the lever arms 98 in place, the anastomosis device 80 is held in a clamped-shut position. In that position, the U-shaped members 84, 86 “clamp the side wall of the target vessel 102” from the within the lumen of the target vessel 102. (Figure 10; column 5, lines 58-59). Thus, the U-shaped members 84, 86 cannot be removed from the target vessel 102 without disengaging from the target vessel 102 and disconnecting the graft vessel from the target vessel. As a result, Yencho does not disclose or suggest removing incision tensioners or any other structure from an incision in the target vessel after grafting.

MPEP 2131 clearly sets forth that claim rejections under 35 U.S.C. §103(a) must be based on the standards established in Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987). In particular, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (emphasis added). Yencho fails to disclose, expressly or inherently, “removing the incision tensioners from the incision after the grafting,” as claimed in claim 1. Thus, each and every element of claim 1 is not set forth in Yencho, and claim 1 is not anticipated by Yencho. The remaining claims depend from claim 1 and thereby include its

limitations, and are thus patentable for at least the same reasons as claim 1. Therefore, the rejection should be reversed by the Board.

Further, the Examiner has acknowledged on the record that "claims 1 and 26 are generic." (Office Action, paper no. 11 ("Second Office Action")). Thus, upon reversal of the rejection of claim 1, claim 1 will be allowable as to all species.

B. The Election Requirement was Improper

Applicants do not appeal the restriction requirement, but do appeal the requirement to elect species, which was traversed in Applicant's response to the First Office Action.¹

The First Office Action set forth no reason for requiring election of species, stating merely that "election of species is required." (First Office Action, page 3).. MPEP 816 states that "[t]he particular reasons relied on by the examiner for holding that the inventions as claimed are...distinct should be concisely stated. A mere statement of conclusion is inadequate." (emphasis added). However, a mere statement of conclusion is all that was provided. By cursorily stating that "election of species is required", the Examiner failed to meet the standards of MPEP 816 for requiring election of species.

In addition, under the Administrative Procedure Act (5 U.S.C. § 706) federal administrative agencies such as the Patent and Trademark Office must support their decisions with substantial evidence for those decisions to be valid:

A reviewing court reviews an agency's reasoning to determine whether it is "arbitrary" or "capricious," or, if bound up with a record-based factual conclusion, to determine whether it is supported by "substantial evidence." *Dickinson v. Zurko*,

¹ The Second Office Action states that "[a]s applicants point out on the applicants' response from page 3 to page 22, it is clearly indicated that the restriction of Species VII of Invention I is proper according to MPEP 806.04(f) Claims Restricted to Species, by Mutually Exclusive Characteristic." (Second Office Action, page 2). However, this statement misapprehends Applicants' Response to Office Action filed on November 8, 2002. Applicants did not "point out" that the restriction was proper, and did not and do not admit that the restriction was proper. Instead, Applicants' extensive Response to Office Action explains why the restriction of Species VII of Invention I was improper.

1999 U.S. Lexis 4004, *24; 527 U.S. 150 (1999) (*citing SEC v. Chenery Corp.*, 318 U.S. 80, 89-93(1943)).

By failing to present any reasoning for requiring election of species, the Examiner acted arbitrarily and capriciously, in violation of the Administrative Procedure Act.

Because the requirement to elect species was improper under MPEP 816 and violated the Administrative Procedure Act, it should be withdrawn.

IX. CONCLUSION

For the above reasons, Applicants respectfully submit that rejection of pending Claims 1, 10-16 and 18 is unfounded. Accordingly, Applicants request that the rejection of Claims 1, 10-16 and 18 be reversed.

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Respectfully submitted,



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APPENDIX

1. A method for grafting a graft vessel to a target vessel during an anastomosis procedure, the method comprising:

- forming an incision in the target vessel;
- placing incision tensioners within the incision in the target vessel;
- tensioning the incision in the target vessel with the incision tensioners;
- grafting the graft vessel to the target vessel while the incision is tensioned; and
- removing the incision tensioners from the incision after the grafting.

10. A method for grafting a graft vessel to a target vessel as recited in Claim 1, wherein the incision is tensioned to a predetermined length which corresponds to a size of the graft vessel to be grafted to the target vessel during the anastomosis procedure.

11. A method for grafting a graft vessel to a target vessel as recited in Claim 1, wherein the operation of tensioning the incision in the target vessel further comprises:

- pulling the incision tensioners with a predetermined force.

12. A method for grafting a graft vessel to a target vessel as recited in Claim 11, wherein the predetermined force is in a range of about .001 N to about 4.5 N.

13. A method for grafting a graft vessel to a target vessel as recited in Claim 1, wherein the incision tensioners are clips which include a first tine and a second tine.

14. A method for grafting a graft vessel to a target vessel as recited in Claim 13, wherein both the first tine and the second tine are configured to penetrate both the graft vessel and the target vessel.

15. A method for grafting a graft vessel to a target vessel as recited in Claim 14, wherein both the first tine and the second tine are configured to rotate such that the first tine and the second tine capture the graft vessel and the target vessel.

16. A method for grafting a graft vessel to a target vessel as recited in Claim 14, wherein both the first tine and the second tine are configured to fold over such that the first tine and the second tine capture the graft vessel and the target vessel.

18. A method for grafting a graft vessel to a target vessel as recited in Claim 1, wherein the tensioning of the incision allows a geometry of the incision in the target vessel to remain constant during the anastomosis procedure.